Plenary Session 3–Non-Governmental Regulatory Aspects

Q&A

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Perry Hackett (University of Minnesota): Greg, what's your take on Golden Rice, because you made a point that, so far, there's nothing to benefit consumers versus the producers or farmers.

Gregory Jaffe: I was in the Philippines in July, visited IRRI[1] and talked to some of the researchers. I saw some of the Golden Rice there. I don't anticipate that there is any food-safety risk from that and I don't think there are any major environmental concerns. The bigger issues are how you get it into the proper communities and make sure they adopt it and use it in their diets. The most important thing is getting it into varieties that yield well and those farmers want to grow. The project seems to be moving forward, and it will be a benefit for those consumers. For consumers in the United States, some high-oleic-oil soybean and other things are beginning to come out and those may be perceived by consumer as benefits, including my organization[2]. But, to date, most of the crops around the world have not been seen as beneficial.

Michael Kahn (Washington State University): A question for Jeff, but the others may want to comment too. With regard to risk, there is one smoking gun out there—that I am aware of—and that is the Showa Denko tryptophan nutritional supplement that caused

[1]The International Rice Research Institute.
[2]Center for Science in the Public Interest (CSPI).

a lot of problems in the early 1980s. The supplement, sold over the counter, in some way generated high levels of neurotoxic compounds. They eventually settled and paid a lot of damages. The irony is that this is still a possibility, because nutritional supplements are not regulated by FDA, except after the fact. After the damage is done, you pull a harmful compound off the market. So, with regard to Jeff, yes there could be risks out there, but the focus of the system on the process of getting to market as opposed to the risks that exist in the market—or the quality of the product—is a problem that is not being addressed. Would you comment on that, from the standpoint of risk?

Jeff Wolt: I will try to. I think you are saying that we need to be cautious. We cannot be cavalier in our approach to these products as they come to the market. You pointed out a good example of where, from a societal standpoint, with our process focus we are missing the perspective of what we are responsible for in seeking out risk. Why do we look so closely at genetically engineered crops when food supplements are largely ignored? There's a disconnect within our regulatory process. It's due to the complexity in the way we regulate things and the fact that they are dispersed over so many agencies and subparts of agencies. We need to always be open to the potential for risks, but we are so often constrained by the regulatory remits within our governmental agencies that we misdirect our attention.

Brian Larkins (University of Nebraska): I'll preface this by saying that I am not an economist and I'm not a sociologist. I am ignorant of a lot of things, but it strikes me that we need a new strategy. It might be simpler just to label things. Many things appear on labels on packages and for the kinds of ingredients that we are talking about—principally corn, soy, and maybe cotton—they are refined products. Why not just put something on there such as, *This food contains ingredients from genetically modified crops that are generally recognized as safe*? I think that, within a very short time, consumers who bother to read labels would not be so concerned. Is the cost of not labelling worth what we are paying in terms of regulation and delay in future technologies that could be very useful to society?

Wolt: This is problematic for me because, as a risk assessor and scientist, I have long adhered to FDA's position that the information on food labels should have a bearing with regard to consumer safety. They are not always able to do that, but the intent is to label in that way. Once we open the floodgates and allow information on the label that is broader than safety, we distract the consumer and we weaken the strength of the label. However, I do have mixed feelings on this because labeling of GM foods has been reshaped by the protest industry over time, from a science issue to a choice issue. All of us are sympathetic to the idea of choice, and so, having labeling as a choice issue, tends to resonate. On the other hand, I'm afraid that labeling and the advent of labeling—which I believe is going to happen—won't be the last salvo in this war. It will be just one step along the way. Those who are aligned against GM technology and foods derived from GM crops will simply use it as the next step in their campaign to denigrate and stigmatize this technology.

Drew Kershen: I think they are quite distinct issues. Labelling really has no impact on the regulatory system as a practical matter. Labeling laws are not going to affect, in any way, the ability to move these crops to market in a quicker or more efficient or less costly way. In Europe, the advent of labeling meant that the processor simply stopped accessing any food that had an ingredient that required the food to be labeled, and it has had a tremendously detrimental impact. It was perceived to be a worry about loss of market and a worry about stigma. I think the United States would likely be very similar to that; it would be used by the protest industry as a way of stigmatizing and a way of then making certain that it was a market-share issue. Of course, you can do this anyway in terms of pressure. You may know that there is pressure on all sorts of food companies to drop ingredients that come from genetically modified crops or genetically modified animals. And so, it's unlikely to solve anything and I agree with Jeff that it would be used as another hammer to stigmatize agricultural biotechnology. Food companies are very worried about that. There are several issues along that same line. You could consider trade issues in similar fashion. The issue is *what would be the impact on these crops?* The protest industry is intent on using this to drive agricultural biotechnology out of the market, by making it impossible to sell these foods. That's their goal. That's what they want to do. That is why they are labeling. They are allied with the organic industry, which sees this as a way of increasing their market share significantly. With those two allies doing that, I don't favor labeling. Along the lines Jeff has said, *what is the purpose of the label?* The goal is to provide effective, clear information to consumers so that they have safe foods.

Jaffe: I agree with Jeff and Drew. At CSPI, we don't support mandatory government-imposed labels except in situations where a safety or nutritional issue dictates it. Labeling shouldn't be a surrogate for safety; if there is an issue of safety we should have a regulatory process to determine that the food is safe before it goes into the supermarket. As a parent, I want to know that everything in the supermarket is safe to eat. I can then choose among different labeled foods for different philosophies or religion or other reasons I have, but I don't say, "We're not going to have a regulatory process, but we'll label it and people can choose whether or not they want to eat it, whether they think it is safe or not." I don't think that is the proper public policy. With that in mind, though, I do advocate to all in the food chain that transparency is very important. Consumers have a point when they ask, "If this is safe why are you hiding it from me?" Whether it's voluntary labeling on the package, or it's on a website on the internet, or it's in a barcode you can read with your smartphone, I do think that, for the person who wants the information, it shouldn't be hidden. One way forward is better transparency.

Kershen: Let me add to that. Transparency might in fact work the way Greg has just described it, if, in fact, we are willing to be transparent about the reality of genetically modified organisms. For example, we would have to drop the distinctions Europe makes between a food made *with* a GMO and a food made *from* a GMO, and that prepositional difference matters tremendously. A food made *from* requires a label. A *from* food is, for

example, a canola oil that has no trace of the transgenic DNA or chemistry. That has to be labeled because it's *from*. However, many cheeses, and wines are made *with* enzymes that are genetically modified. The leading enzyme company in the world is Novozymes of Denmark, which produces many enzymes and if you were to label every food produced with those enzymes, it would be almost 100% and then it would become irrelevant.

Steve Pueppke: We've had good discussion on this. Let's try to get a couple more questions in.

Tom Turpen (Citrus Research and Development Foundation): I'd like the panel to continue to throw out ideas on how to reframe the discussion for public opinion, because that seems to be so key to regulatory reform. It has two parts. First, who is the voice? Who speaks for this? I think the NABC has a unique role to play, particularly if on the same page with the NRC study that is in process. The National Academy, the USDA and NABC would provide a powerful voice. But then, you still have to address the content. What positive content will sway public opinion? For citrus greening, we need a sustainable solution and it's got to be genetic in the long term. However, it's not at all clear who is going to pay for tree replacement. It's not just the public sector that is priced out of that equation. It's also the private sector. That's bad enough for seed crops, but for permanent crops it doesn't make financial sense which means it won't get done. This means that food is going to be more scarce and more expensive, and yet cost always seems to be way down the list of anyone's themes to talk about. I want to hear ideas about how to communicate for public opinion with positive themes that are going to resonate. We need an anti-Frankenfood poster; what is the counter opinion that is equally effective to that messaging? We have poverty and hunger in our country too. It's not just a developing-world problem. Why isn't that part of the discussion?

Jaffe: Citrus greening, if that ends up being a genetically engineered solution will be viewed as a tremendous consumer benefit, if it is properly presented to the public. The major question, when you are talking about this technology is, "Why are you doing this?" People haven't talked about cost because these are commodity crops, and the cost of the cornflakes in the box isn't relevant. I think if consumers have the choice of American orange juice versus Brazilian orange juice and Brazilian orange juice is twice as expensive, I think they will choose American orange juice—no question about that. In addition to cost, they care about "American." A new thing now is labeling things that are not imported. Nobody wants stuff from China and that's another selling point. Properly answering *why are you doing this* is important for the public because many suspect that somebody is tinkering with something because they can do it rather than for a good reason. Secondly is the public aspect of it. If things are done by a multinational corporation, consumers are more hesitant than if they are done by a small company or by a public university. I was sorry when everybody was saying *we're going to do the public stuff but then we are goingto license the IP to the big companies*. I think that is not advantageous. Why not license to

some small companies? I think that small companies may be perceived differently. And the third thing I'd mention is education, such as provided by NABC members: education about agriculture in general. Where does our food come from? I think most Americans are like me; I grew up in the suburbs of New York City and now I live in the suburbs of Virginia, far away from farms. Many consumers don't understand what scientists do for agriculture and what farmers do and what their work involves. One of my suggestions was going to be *put things in context*, but the public has the context of "Old McDonald had a farm" and everything else sounds scary by comparison. Context is really important.

B.J. Haun (Cellectis Plant Sciences): An interesting thing was brought up by Drew about USDA having an exempt category, and an interesting point was made about people thinking that the ruby red grapefruit is organic. There's a double-edged sword there which I would like the panel's opinion on. If you make these exempt categories you would actually reduce transparency, whereas transparency is what allowed the ruby red grapefruit to be considered natural. Going down the path of listing exempt categories, is that a good thing or a bad thing? Is that going to make certain things that industry and the public sector make more readily received? Will less transparency give the NGO's even more ammunition against us?

Kershen: The theory has been that if the government regulates it, people have confidence in it. I think that that has been proven incorrect. You regulate because it's not safe and you are dealing with safety. So, there is no need to regulate when there is not a safety issue. In fact, to do so miss-educates the public, miss-educates them in a fundamental way because it is really against transparency. It's like the headlines you get on the internet; many are simply incorrect and biased. So, I think the answer is, we've gone down that route, it's been tested, it's been proven that if you regulate that, in fact, you are giving the wrong message, you educate the public incorrectly. Therefore, one way to deal with this is, in fact, to say, "It's time to change the regulatory paradigm."

Donald Weeks (University of Nebraska): Greg, you indicated that you thought that there could be a chance for redoing the regulatory system. Some of us are of the opinion that, once the regulatory system has been put in place, it's not going to be displaced because of its—I don't know the right word to use—it's permanency. Are there chances for redoing the regulatory system, or are we fantasizing if we think about that?

Jaffe: Changing regulatory systems is tough to do, but it does happen. The Food Safety Modernization Act was signed into law in 2011 to revise what were outdated food-safety laws and to change the power that FDA has and how they regulate different things, with emphasis on produce, which was causing lots of outbreaks, and less emphasis on other things that weren't causing outbreaks but were maybe covering food-safety problems in the 1950s. Whether that's likely to happen in the immediate future for biotech, I'm not sure there is sufficient interest. But, I think it would be better.

Wolt: A quick word of caution—be careful what you wish for. I think that most of us who deal in regulatory-related arenas are cautious in encouraging change in regulations, because you really don't know what the repercussions are going to be down the road. It might be better to live with what you've got than to wish for a new day. The Food Quality Protection Act is a good example. There was a big push by a lot of parties to move that through to, essentially, update our regulatory approach to pesticides, and unintended consequences have made things somewhat more difficult in terms of our ability to use modern chemical pesticides. So, I think there is an opportunity to change regulations, but what you wish for and what you get may be two different things.

Pueppke: Let's give Mike Kahn the last question.

Kahn: With regard to changing the regulatory climate, one can go back a few years to the Delaney Amendment, which was aimed at keeping all cancer-causing compounds out of food. However, with improvements in analytical technologies, it turns out that cancer-causing compounds are in all food at some level. And so, that particular regulatory paradigm had to be broken because it didn't make any sense. In fact, it was essentially redefined as *there's a minimum kind of background, cosmic rays or something like that, that creates a hazard and you are not going to get below that. You shouldn't be regulating to the nth degree when there are these other things present.* Somebody pointed out that some of the results of this editing technology are indistinguishable from natural mutations. If you knock four bases out of a promoter, you can't tell whether that was done with CRISPR or TALEN or a zinc-finger nuclease or it just happened to a plant that was growing out in the field. We are getting to the point where this kind of product distinction makes no sense—to distinguish recombinant DNA from natural products. I think there is a need for redefinition to incorporate that kind of realization.

Kershen: I agree, but I don't think that the law will necessarily make the same distinction that you just made. And I say that because when you look at the EU regulations, particularly regulation 1830/2003 on labeling and traceability, it requires that anything that meets the definition of genetic modification—even though it is not in the final product—you've got to provide a paper trail for labeling purposes. If you use a technique that is regulated within that system, the fact that you won't be able to detect it at the end will be irrelevant because the food people and the food developers who put this on the market are required to provide a paper trail that comes with an enforcing mechanism with both civil and criminal penalties. As a lawyer, I would be very adverse to advising my client *they'll never find it* because, I guarantee you, there are NGOs who are looking every day to find it to punish you and they will find it, in which case I'll be in the European court with my client. I have a theory about representing clients: they go to jail, I go home. I'll be trying to keep my client out of jail, but if I fail, I'll say, "I hope you find good wine in your French cell."